submitted under §§ 10.30 and 821.2(b) of this chapter, requesting an exemption or variance from medical device tracking requirements in part 821 of this chapter.

[47 FR 38480, Aug. 31, 1982]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 5.31, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 5.32 Authority relating to determination of product primary jurisdiction.

The FDA ombudsman as product jurisdiction officer is authorized to determine whether the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), or the Center for Drug Evaluation and Research (CDER) has primary responsibility for premarket review and regulation of a product that constitutes a combination of a drug, device, or biological product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act or that is a drug, device or biologic product where the center with primary jurisdiction is unclear or in dispute.

[56 FR 58758, Nov. 21, 1991]

§ 5.33 Premarket approval of a product that is or contains a biologic, a device, or a drug.

For a product that is or contains a biologic, a device, or a drug, the following officials in the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, or Center for Drug Evaluation and Research who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Biological Product Review, CBER.

(b) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH) and the Director, Office of Device Evaluation, CDRH.

(c) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER); the Director, Pilot Drug Evaluation Staff, CDER; and the Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

[56 FR 58759, Nov. 21, 1991]

§ 5.34 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.

(a) Each center director is authorized to select members of, and consultants to, scientific and technical FDA advisory committees under that center's management to serve temporarily as voting members on another advisory committee under that center's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees if such voting members are serving on an advisory committee managed by another center has not been redelegated. This authority will continue to be exercised by the Commissioner or his designee.

(b) Each center director is authorized, under 18 U.S.C. 208(b)(1), to sign conflict of interest waivers for special government employees without substantial interest to serve as consultants to advisory committees or in any other capacity within the centers except as advisory committee members.

[58 FR 39142, July 22, 1993]

§ 5.35 Enforcement activities.

(a) Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA–200A, Identification Record, and Form FDA–200B, Specification of General Authority, are authorized: